



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-D-0575]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry on Expedited Programs for Serious Conditions--Drugs and Biologics

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202-395-7285, or emailed to oir_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0389. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-5733, PRASStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Guidance for Industry: “Expedited Programs for Serious Conditions--Drugs and Biologics”

OMB Control Numbers 0910-0389 and 0910-0765--Revision

This information collection supports the previous captioned Agency guidance. The guidance provides a single resource for information on FDA’s policies and procedures related to the following expedited programs for serious conditions: (1) fast track designation, (2) breakthrough therapy designation, (3) accelerated approval, and (4) priority review designation. The guidance describes threshold criteria generally applicable to expedited programs, including what is meant by serious condition, unmet medical need, and available therapy. The guidance addresses the applicability of expedited programs to rare diseases, clarification on available therapy, and additional detail on possible flexibility in manufacturing and product quality. The guidance also clarifies the qualifying criteria for breakthrough therapy designation and provides examples of surrogate endpoints and intermediate clinical endpoints used to support accelerated approval.

In the *Federal Register* of November 8, 2017 (82 FR 51846), we published a 60-day notice requesting public comment on the proposed extension of this collection of information. No comments were received. We therefore estimate the burden of the information collection as follows:

Table 1.--Estimated Annual Reporting Burden¹

Guidance for industry: Expedited programs for serious conditions--Drugs and biologics	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Priority review designation request (0765)	48	1.7	82	30	2,400
Breakthrough therapy designation request (0765)	87	1.29	113	70	7,910
Fast track designation request (0389)	140	1.33	187	60	11,220

Fast track premeeting packages (0389)	107	1.23	132	100	13,200
Total	34,730				

¹There are no capital costs or operating and maintenance costs associated with this collection of information.

The information collection elements regarding priority review designation and breakthrough therapy designation requests are reflected in rows 1 and 2 of table 1 and are currently approved under OMB control number 0910-0765. Meanwhile, fast track designation requests and premeeting packages are currently approved under OMB Control No. 0910-0389. We are therefore revising OMB control number 0910-0389 to include all four collection elements. Information collection burden for accelerated approval requests is currently approved under OMB control numbers 0910-0001 (drugs) and 0910-0338 (biologics). The estimates provided are based on our experience with the respective collection elements over the past 3 years.

A sponsor or applicant who seeks fast track designation is required to submit a request to the Agency showing that the drug product: (1) is intended for a serious or life-threatening condition, and (2) has the potential to address an unmet medical need. The Agency expects that most information to support a designation request will have been gathered under existing requirements for preparing an investigational new drug (IND), new drug application (NDA), or biologics license application (BLA). If such information has already been submitted to the Agency, the information may be summarized in the fast track designation request. A designation request should include, where applicable, additional information not specified elsewhere by statute or regulation. For example, additional information may be needed to show that a product has the potential to address an unmet medical need where an approved therapy exists for the serious or life-threatening condition to be treated. Such information may include clinical data, published reports, summaries of data and reports, and a list of references. The amount of

information and discussion in a designation request need not be voluminous, but it should be sufficient to permit a reviewer to assess whether the criteria for fast track designation have been met.

After the Agency makes a fast track designation, a sponsor or applicant may submit a premeeting package that may include additional information supporting a request to participate in certain fast track programs. The premeeting package serves as background information for the meeting and should support the intended objectives of the meeting. As with the request for fast track designation, the Agency expects that most sponsors or applicants will have gathered such information to meet existing requirements for preparing an IND, NDA, or BLA. These may include descriptions of clinical safety and efficacy trials not conducted under an IND (e.g., foreign studies) and information to support a request for accelerated approval. If such information has already been submitted to FDA, the information may be summarized in the premeeting package.

The Agency estimates the total annual number of respondents submitting requests for fast track designation is approximately 140, and the number of requests received is approximately 187 annually. FDA estimates that the number of hours needed to prepare a request for fast track designation is approximately 60 hours per request (row 3 in table 1).

Of the requests for fast track designation made per year, the Agency granted approximately 132 requests from 107 respondents, and for each of these granted requests, a premeeting package was submitted to the Agency. FDA estimates that the preparation hours are approximately 100 hours per premeeting package (row 4 in table 1). The total burden hours for fast track designation and fast track meetings has increased due to increased requests; however, the hours per request have remained the same.

Dated: February 1, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018-02415 Filed: 2/6/2018 8:45 am; Publication Date: 2/7/2018]